Claim Rejections -35 USC § 102

(1) Claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al (US 5,447,724).

Helmus was cited for teaching all the claimed subject matter including an implantable medical device (col. 9, lines 59-60), having a tissue-contacting surface formed of polyurethane or silicone (col. 2, lines 41-42) which has a drug such as heparin (col. 6, line 51) or a steroid (col. 6, line 56) intimately mixed into it (col. 4, lines 20-24 and col. 9, lines 45-46), wherein the drug makes up 2% by weight of the material (col. 10, lines 12-13, and 62).

Applicants' respectfully traverse. Helmus does not appear to teach the tissue-contacting polymer surface of the catheter is intimately mixed with the drug. Helmus has two layers. A outer polymeric surface-layer overlying a inner polymer layer that incorporates the agent (23) (see figures 1b and 1c, or 2b and 2c). The outer-layer has an elutable component (22) which is eroded to form pores to the inner polymer area containing agent (23). No where is there formed an outer polymer layer intimately mixed with the drug.

By having an outer polymer layer coating the active drug layer one skilled in the art would recognize that Helmus actually teaches away from directly mixing the drug with the surface polymer. Applicants thereby respectfully, request removal of the present rejection, and claims 13, 15, 16, 24, 27, 29, 33, 34, 36, 39, and 41 be allowed to issue.

Claim Rejections -35 USC § 103

(1) Claims 37, and 43 were rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724).

Helmus was indicated to teach all the claimed subject matter except for the slightly lower concentrations in claims 37 and 43. Helmus was cited for teaching 2% of the material is the drug, whereas the claims call for a maximum of 1 %. In

a tissue-contacting wall of a catheter, based on the specific material that the drug is being mixed into, and also how the catheter was formed (i.e. extrusion process, etc.). Therefore, the examiner takes the catheter was formed (i.e. extrusion process, etc.). Therefore, the examiner takes the position that it would have been obvious to one of ordinary skill in the art to vary the weight percentage of a drug such a small amount in order to achieve a desired release rate depending the polymer being used and the manufacturing on process (temperature, curing, etc) used to make the catheter.

Applicants respectfully traverse. As previously discussed above, Helmus teaches the active agent is placed beneath an overcoat polymer layer. The overcoat layer that has an elutable component (22), that when eluted forms pores that allow for the release of agent through the pores. No where is there formed an outer polymer layer intimately mixed with the drug.

Because Helmus does not describe or suggest applicants invention, Applicants thereby respectfully, request claims 37 and 43 be allowed to issue.

(2) Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chait (US 5, 727 ,555) in view of Helmus et al (US 5,4471 724).

Chait was cited for teaching a catheter having an external fitting coupled to the proximal end, and helical coils as claimed. However, Chait was found to lack a layer with anti-inflammatory agent in it. Helmus teaches an elongate body-inserted member with an anti-inflammatory agent imbedded in the tissue-contacting surface as discussed supra. It would have been obvious to one having ordinary skill in the art to form the catheter of Chait with the layered structure of Helmus in order to reduce inflammation in the treatment area, since formation of catheters with layers and with drug-saturated layers is well known in the art of catheters.

Applicants again respectfully traverse. As previously discussed in our last response, the Chait reference has the same deficiency as Helmus. Neither Chait or Helmus provides for the active agent to be intimately mixed with polymer which is in contact with the tissue. Further, although there is casual mention to

use of steroids, Chait uses the steroids as an anti-proliferative agent, not as an anti-inflammatory agent.

Because Chait in view of Helmus does not teach or suggest the claimed invention, Applicants respectfully request the present rejection to claim 14 be removed, and claim 14 be allowed to issue.

(3) Claims 17-19, 38, and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al (US 5,447,724) in view of Fearnot et al. (US 5,609,629).

Helmus was again cited for teaching all the claimed subject matter except for the steroid being a glucocortiocosteroid such as dexamethasone. Fearnot was cited for teaching the use of dexamethasone in a drug embedded outer layer of a catheter. It would have been obvious to one of ordinary skill in the art to use dexamethasone as taught by Fearnot as one of the steroids broadly mentioned by Helmus (col. 6, line 56) since dexamethasone is a well known anti-inflammatory steroid, and as demonstrated by Helmus it is know to use it as the bioactive component of a bioactive surface on a catheter.

As previously mentioned in our last response, Fearnot teaches a coated medical device with a releasable bioactive under layer, however, like Helmus and Chait, it accomplishes the release by adding a porous coating layer over the bioactive layer. Non of the references appear to teach or suggest intimately mixing the active layer as part of the outer layer.

Because Helmus in view of Fearnot does not teach or suggest the claimed invention, Applicants respectfully request the present rejection over Helmus in view of Fearnot be removed and the claims be allowed to issue.

Summary

Applicants believe their present response address the outstanding issues presented by the examiner and respectfully request the present claims be allowed to issue.

Respectfully submitted,

Kenneth J. Collier 2/26/02

Kenneth J. Collier
Attorney/Agent for Applicant(s)
Registration No. 34,982
Phone: 763-505-2521

Medtronic, Inc.
Patent Department
710 Medtronic Parkway NE
Minneapolis, MN 55432-5604

AMENDED CLAIMS

(Version with Markings To Show Changes Made)

13. An indwelling catheter comprising:

an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; and

an external fitting coupled to the proximal end;

wherein the tissue-contacting surface of the elongate body comprises a polymer in which a steroidal anti-inflammatory agent is intimately mixed, the steroidal anti-inflammatory agent being present in a concentration of between .1% and 5% of the steroidal agent in the polymer (w/w).

14. The indwelling catheter of claim 13 further comprising one or more helical coils formed in the elongate body between the proximal and distal ends.

15. The indwelling catheter of claim 13 wherein the polymer is selected from the group of polyurethanes, silicones, polyamides, polyimides, polycarbonates, polyethers, polyesters, polyvinyl aromatics, polytetrafluoroethylenes, polyolefins, acrylic polymers or copolymers, vinyl halide polymers or copolymers, polyvinyl ethers, polyvinyl esters, polyvinyl ketones, polyvinylidine halides, polyacrylonitriles, copolymers of vinyl monomers with each other and olefins, and combinations thereof.

16. The indwelling catheter of claim 15 wherein the polymer is selected from the group of polyurethanes, silicones, or combinations thereof.

17. The indwelling catheter of claim 13 wherein the anti-inflammatory agent is a glucocorticosteroid.

18. The indwelling catheter of claim 17 wherein the glucocorticosteroid is selected from the group of cortisol, cortisone, fludrocortisone, Prednisone, Prednisolone, 6α-methylprednisolone, triamcinolone, betamethasone, dexamethasone, beclomethasone, aclomethasone, amcinonide, clebethasol, clocortolone, derivatives thereof, and salts thereof.

19. The indwelling catheter of claim 18 wherein the glucocorticosteroid is dexamethasone, a derivative thereof, or a salt thereof.

24. The indwelling catheter of claim 13 wherein the tissue-contacting surface further includes heparin.

27. A method of modulating tissue encapsulation of an indwelling catheter comprising implanting the indwelling catheter into a patient, wherein the indwelling catheter comprises:

an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; and

an external fitting coupled to the proximal end;

wherein the tissue-contacting surface of the elongate body comprises an overcoating of a polymer in which a steroidal anti-inflammatory agent is intimately mixed at a concentration of between .1% and 5% of the steroidal anti-inflammatory agent in the polymer (w/w).

29. A method of modulating degradation of an indwelling catheter comprising implanting the indwelling catheter into a patient, wherein the indwelling catheter comprises:

an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; and

an external fitting coupled to the proximal end;

wherein the tissue-contacting surface of the elongate body comprises a polymer intimately mixed with a steroidal anti-inflammatory agent and wherein the solid weight of the steroidal anti-inflammatory agent is between .1% and 5% of the total solid combined weight of the polymer and the steroidal anti-inflammatory agent.

33. A method of making an indwelling catheter comprising:

providing an elongate body having a proximal end, a distal end, a tissue-contacting surface, and at least one interior lumen therethrough; wherein the tissue-contacting surface comprises an overcoat of a polymer intimately mixed with a steroidal anti-inflammatory agent [is incorporated] at a concentration of between .1% and 5% of the steroidal anti-inflammatory agent in the polymer (w/w); and

coupling an external fitting to the proximal end of the elongate body.

34. The method of claim 33 wherein the step of providing an elongate body comprises intimately mixing the steroidal anti-inflammatory agent with the polymer in a solvent and applying the mixture to the elongate body to form a tissue-contacting surface.

36. The catheter of Claim 13, wherein the polymer is a non-porous polymer.

37. The catheter of Claim 13, wherein the steroidal anti-inflammatory agent is between .1% and 1% of the total solid combined weight of the polymer and the steroidal anti-inflammatory agent.

38. The catheter of Claim 37, wherein the steroidal anti-inflammatory agent is selected from the group consisting of dexamethasone and beclomethasone.

39. The catheter of Claim 13, wherein the steroidal anti-inflammatory agent is impregnated into the polymer of the tissue-contacting surface.

41. The method of Claim 29, wherein the steroidal anti-inflammatory agent is impregnated into the polymer of the tissue-contacting surface.

43. The method of Claim 29, wherein the steroidal anti-inflammatory agent is between .1% and 1% of the total solid combined weight of the polymer and the steroidal anti-inflammatory agent.

44. The method of Claim 43, wherein the steroidal anti-inflammatory agent is selected from the group consisting of dexamethasone and beclomethasone.